Marked-Up Version of Amended Claims 11 and 35

11 (Twice Amended). A programmable blood processing system coupled to a blood separation device comprising

a cassette containing first and second preformed, pneumatically actuated pump stations, more than two preformed fluid flow paths, and more than two preformed, pneumatically actuated valves in the fluid flow paths, the system being configured to place a first pump station in communication with any fluid flow path and a second pump station in communication with any fluid flow path,

a control program, and

a programmable pneumatic actuator to hold the cassette and selectively apply pneumatic force to the valves and pump stations in response to [a] the control program to direct fluid flow through any selected pump station in either a forward direction between two valves, or a reverse direction between two valves, or an in-out direction through a single valve.

35 (Twice Amended). A blood processing method comprising the steps of

providing a cassette containing first, [and] second, and third preformed, pneumatically actuated pump stations, more than [two] three preformed fluid flow paths, and more than [two] three preformed, pneumatically actuated valves in the fluid flow paths, whereby the first pump station may be placed in flow communication with any fluid flow path and the second pump station may be placed in flow communication with any fluid flow path, and the third pump station may be placed in flow communication with a venipuncture, and

placing the cassette in association with a pneumatic actuator to selectively apply pneumatic force to the valves and pump stations,

providing a first selectable control program to operate the pneumatic actuator to perform a first desired blood processing procedure using the cassette including conveying blood from the venipuncture through a separation device for separation into a first component part and a second component part, at least a portion of [which] the first component part is collected, and at least a portion of the second component part is returned through the venipuncture, and

providing a second selectable control program to operate the pneumatic actuator to perform a second desired blood processing procedure different than the first desired blood

processing procedure using the cassette including conveying blood from the venipuncture through a separation device for separation into a first component part and a second component part, at least a portion of [which] the second component part is collected, and at least a portion of the first component part is returned through the venipuncture.

REMARKS

Claims 1 to 10 have been cancelled. Claims 11 and 35 have been amended. In compliance with 37 C.F.R. §121(c)(3), a clean version of the entire set of pending claims is being submitted, as is a marked-up version showing changes in the amended claims relative to the previous version of the claims.

Claims 11 to 38 remain in the application. Of these, claims 11, 16 and 25 are independent apparatus claims and claim 35 is an independent method claim.

Claims 11 to 38 stand rejected based upon various combinations under 35 U.S.C. §102(b) based upon Kamen et al. U.S. Patent 5,628,908 (Kamen '908) and under 35 U.S.C. §103(a) based upon Kamen '908 in view of Dennehey et al. U.S. Patent 5,462,416 (Dennehey '416) or Kamen '908 in view of Dennehey '416 and further in view of Brierton et al. U.S. Patent 5,795,317 (Brierton '317).

Kamen does not teach or suggest a programmable blood processing system, as defined in amended claim 11, comprising a cassette containing first and second preformed, pneumatically actuated pump stations, more than two preformed fluid flow paths, and more than two preformed, pneumatically actuated valves in the fluid flow paths, which is configured to place a first pump station in communication with any fluid flow path and a second pump station in communication with any fluid flow path, and in which a programmable pneumatic actuator selectively applies pneumatic force to the valves and pump stations in response to a control program to direct fluid flow through any selected pump station in either a forward direction between two valves, or a reverse direction between two valves, or an in-out direction through a single valve. In Kamen, the valve stations V1 to V4 serve only the upper ports of the pump chambers P1 and P2. These valve stations, in turn, serve only the noncritical liquid paths F1 and F2, conveying fluid from the patient (see, e.g., Column 10, lines 18 to 26). Likewise, the valve stations V5 to V10 serve only the lower ports of the pump chambers P1 and P2. These valve stations, in turn, serve only the critical liquid paths F3, F4, and F5, conveying fluid toward the patient (see, e.g., Column, lines 44 to 52). The exclusivity of this arrangement in Kamen is underscored by the repeated use of the term "only." Under control of the pneumatic actuator, the pump stations in Kamen accommodate only one-way flow, in from the noncritical paths and out

through the critical paths. Neither the pump stations nor the pneumatic actuator in Kamen are configured to direct fluid flow through any selected pump station in either a forward direction between two valves, or a reverse direction between two valves, or an in-out direction through a single valve. Claim 11 defines a system this is structurally different than Kamen's system, and which performs a function that Kamen's system does not teach or suggest and is not inherently capable of performing.

Kamen also does not teach or suggest a programmable blood processing system or method, as defined in claims 16, 25, and 35, that includes a cassette containing first, second, and third preformed, pneumatically actuated pump stations, more than three preformed fluid flow paths, and more than three preformed, pneumatically actuated valves in the fluid flow paths, and in which a programmable pneumatic actuator selectively applies pneumatic force to the valves and pump stations in response to a control program to place the first pump station in flow communication with any fluid flow path and the second pump station in flow communication with any fluid flow path, to simultaneously place two of the pump stations in flow communication with the blood separation device, while further simultaneously placing the third pump station in flow communication with a venipuncture. Kamen discloses a cassette with two pump stations for exchanging peritoneal dialysis solution. Kamen does not teach or suggest a blood processing system coupled to a blood separation device that includes a cassette to direct blood through three pneumatically actuated pump stations, more than three preformed fluid flow paths, and more than three preformed, pneumatically actuated valves, and in which a programmable pneumatic actuator selectively applies pneumatic force to simultaneously place two of the pump stations in flow communication with the blood separation device, while simultaneously placing the third pump station in flow communication with a venipuncture. Claims 16 and 25 define a system that is structurally different than Kamen's system. These claims and method claim 35 define functions that are different than the functions that Kamen's system performs, and which Kamen's system is not inherently capable of performing. In Dennehey '416 and Brierton '317, blood processing systems are disclosed, but there are no preformed, pneumatically actuated pump stations, and there is no motivation in these documents leading one to substantially redesign the cassettes of Dennehey or Brierton by removal of the

peristaltic tube loops and their replacement with preformed, pneumatically actuated pump stations.

A Supplemental Information Disclosure Statement accompanies this Amendment.

Allowance of claims 11 to 38 is respectfully requested.

Respectfully submitted,

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May 29, 2003
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